

### **REMARKS**

Applicants respectfully request reconsideration of the present application. Claims 10, 21, 31 and 36 have been amended. Claims 20 and 30 have been canceled. Claims 1-9 have previously been canceled. As such, claims 10-19, 21-29 and 31-40 are pending herein. No new matter has been added to the present application. Claims 10-19, 21-29 and 31-40 are believed to be in condition for allowance and such favorable action is respectfully requested.

### **Claim Rejections – 35 U.S.C. § 103**

Claims 10-11, 14, 16, 21, 24, 26, 31, 34, 36 and 39 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,117,836 to Millar (the Millar Patent) in view of U.S. Patent No. 5,833,603 to Kovacs et al. (the Kovacs Patent). Applicants have amended claims 10 and 21. Claim 10 recites a method for monitoring the cerebral environment of a patient for prognosis comprising monitoring changes of the pH of the CSF within the initial 48 hours following head trauma. Claim 21 recites a method of monitoring at least one characteristic of CSF of a patient for prognosis comprising monitoring changes of the pH of the CSF within the initial 48 hours following head trauma. Applicants submit that neither the Millar Patent or the Kovacs Patent teach or suggest monitoring the pH of CSF within the initial 48 hours following head trauma. Rather, the Millar Patent teaches a method for measuring intracranial fluid characteristics but does not teach or suggest monitoring the pH of CSF. The Kovacs Patent teaches an implantable biosensing transponder for monitoring blood chemistry. The Kovacs Patent does not teach or suggest monitoring the pH of CSF 48 hours following an initial head trauma.

As neither the Millar Patent or Kovacs Patent teach or suggest monitoring changes of the pH of CSF within the initial 48 hours following head trauma, Applicants request

withdrawal of the rejection of claim 10 and 21 under 35 USC 103 (a). As claims 11, 14, 16, 24 and 26 depend either directly or indirectly from independent claims 10 and 21, Applicants request withdrawal of the 103 rejection to these claims as well.

Applicants have also amended independent claims 31 and 36. Amended claim 31 recites an apparatus for monitoring the cerebral environment of a patient for prognosis comprising at least one sensor for measuring pH of CSF within a porous sheath such that CSF flows through the porous sheath and adjacent said sensor . Amended claim 36 recites an apparatus for monitoring at least one characteristic of CSF of a patient for prognosis the apparatus comprising at least one sensor for measuring pH of CSF within a porous sheath such that CSF flows through the porous sheath and adjacent said sensor. Applicants submit that neither the Millar Patent nor the Kovacs Patent teach or suggest at least one sensor for measuring pH of CSF within a porous sheath such that CSF flows through the porous sheath and adjacent said sensor. The porous sheath permits transfer of the CSF to the sensor. The porous sheath aids in allowing CSF to flow adjacent said sensor. The Millar Patent, on the other hand, teaches a transducer tipped catheter. There is no teaching or suggestion that the sensor is within a porous sheath which aids in allowing CSF to flow adjacent said sensor. The Kovacs Patent also does not teach or suggest a pH sensor within a porous sheath such that CSF flows through the porous sheath and adjacent said sensor. Rather the Kovacs Patent teaches a pH sensor that is exposed directly to the external environment or within a glass capsule. (See Column 10, lines 18-26).

As neither the Millar Patent nor the Kovacs Patent teaches or suggests a pH sensor within a porous sheath which aids in allowing CSF to flow adjacent said sensor, Applicants request withdrawal of the 103 rejection as to independent claims 31 and 36. Further,

as claims 34 and 39 depend either directly or indirectly from claims 31 and 36 Applicants request withdrawal of the 103 rejection as to these claims as well.

Claims 13 and 23 have been rejected under 35 USC 103(a) as being unpatentable over the Millar Patent in view of the Kovacs Patent and in further view of U.S. Patent 5,830,188 to Abouleish (the Abouleish Patent). As discussed above the Millar Patent and the Kovacs Patent do not teach or suggest monitoring the pH of CSF within the initial 48 hours following head trauma. The Abouleish Patent also does not teach or suggest monitoring the pH of CSF the initial 48 hours following head trauma. Rather the Abouleish Patent teaches a curved cannula for continuous spinal anesthesia. As the Millar Patent, Kovacs Patent and Abouleish Patent neither teach nor suggest monitoring the pH of CSF 48 hours following the initial head trauma, Applicants request withdrawal of the 103 rejection as to claims 13 and 23.

Claims 17, 19-20, 27 and 29-30 have been rejected under 35 USC 103(a) as being unpatentable over the Millar Patent in view of the Kovacs Patent and in view of U.S. Patent 4,904,237 to Janese (the Janese Patent). As discussed above, the Millar Patent and the Kovacs patent do not teach monitoring the pH of CSF within the initial 48 hours following head trauma. Further, the Janese Patent does not teach or suggest monitoring the pH of CSF the initial 48 hours following head trauma. Examiner states that Millar Patent in view of the Kovacs Patent in further view of Janese Patent does not teach monitoring of the CSF fluid within the initial 24 hours following head trauma. However, it is Examiner's contention that in the art of diagnosis management and/or treatments of cerebral spinal fluid takes place during intra-cranial, trauma to the brain and spinal cord, and fetal intra-cranial hemorrhage. Furthermore, Examiner states the purpose of the invention is to function as a diagnostic tool at such times. The Examiner contends that it would been obvious at the time the invention was made to monitor the cerebral spinal fluid

at times of arterial vasospasm, subarachnoid hemorrhage, trauma to the brain and spinal cord to use the combination to provide diagnostic aid at these items. Applicants respectfully disagree. There is no teaching or suggestion in the Janese Patent that monitoring the pH of CSF fluid within the initial 48 hours following the initial head trauma will be beneficial as a diagnostic aid or for treatment. The Janese Patent merely teaches that the pH is monitored. According to an embodiment of the present invention, monitoring the pH within the initial 48 hours following head trauma helps predict the outcome of head trauma. However, it is difficult to predict in the what measurements will be beneficial as diagnostic aids and when these measurements should be taken. So, while it might have been **obvious to try to measure the pH of CSF fluid within the initial 48 hours** following head trauma, there is no teaching or suggestion in the Janese patent that monitoring the pH of CSF within 48 hours following the initial head trauma would function as a diagnostic tool or aid the patient.

According to In re Antonie, obviousness cannot be based upon what a person skilled in the art might try or might find obvious to try, but rather must consider what the prior art would have led a person skilled in the art to do. 559 F.2d 618 (CCPA 1977). In this case, while it might have been obvious to try to measure the pH of CSF fluid within 48 hours following initial head trauma it was not known that measuring the pH of CSF within the initial 48 hours following head trauma would act as a diagnostic aid and help in predicting the outcome of head trauma.

As neither the Millar Patent, Kovacs Patent nor Janese patent teach or suggest measuring the pH of CSF fluid within the initial 48 hours head trauma, Applicants request withdrawal the 103 rejection as to claims 17, 19, 27 and 29. As claims 20 and 30 have been canceled the rejection should be moot as to those claims as well.

Claims 10-12, 15, 21-22, 25, 31-33 and 36-38 have been rejected under 35 USC 103 (a) as being unpatentable over the Kovacs patent in view of U.S. Patent 4,903,707 to Knute et al. (the Knute patent) With respect to independent claims 10 and 21, as discussed above the Kovacs patent neither teaches nor suggest monitoring the pH of CSF 48 hours following the initial head trauma. Further, the Knute Patent neither teaches nor suggests monitoring the pH of CSF within the initial 48 hours following head trauma. Rather the Knute Patent teaches a ventricular catheter assembly having a catheter for insertion through an opening in a skull for monitoring a parameter of a brain in a living person.

As neither the Kovacs Patent nor the Knute Patent teach or suggest monitoring the pH of CSF 48 hours following the initial head trauma, Applicant request withdrawal of the 103 rejection of claims 10 and 21. As claims 11-12, 15, 22 and 25 depend either directly or indirectly from claims 10 and 21, Applicants request withdrawal of the rejection as to these claims well.

With respect to independent claims 31 and 36, as discussed above the Kovacs patent neither teaches nor suggests a pH sensor within a porous sheath such that CSF flows through the porous sheath and adjacent said sensor. Further, the Knute Patent neither teaches nor suggests a pH sensor within a porous sheath such that CSF flows through the porous sheath and adjacent said sensor. Rather, the Knute Patent teaches a ventricular catheter assembly having catheter for insertion through an opening in a skull for monitoring a parameter of a brain in a living person. The Knute Patent does not teach or disclose a pH sensor.

As neither the Kovacs Patent nor the Knute Patent teach or suggest a pH sensor within a porous sheath such that CSF flows through the porous sheath and adjacent said sensor, Applicants request withdrawal of the 103 rejection to claims 31 and 36. As claims 32-33 and 37-

38 depend either directly or indirectly from claims 31 and 36, Applicants request withdrawal of the 103 rejection as to these claims as well.

Claims 18, 28, 35 and 40 have been rejected under 35 USC 103 (A) as being unpatentable over the Kovacs Patent in view of the Knute Patent and in further view of the U.S. Patent 5,403,746 to Bentson et al. (the Bentson Patent) and Re 31,879 to Lubbers et al. (the Lubbers Patent). As discussed above, with respect to independent claims 10 and 21, the Kovacs Patent and the Knute Patent neither teach nor suggest monitoring the pH of CSF 48 hours following the initial head trauma. Rather, the Bentson Patent teaches an optical fluorescence based sensor for measuring the concentration of a gas in a medium which has improved drift stability. The Lubbers patent teaches a method and an arrangement for measuring the concentration of gases in a sample including the generation of a monochromatic light beam having predetermined color characteristic.

As the Kovacs Patent, Knute Patent, Bentson Patent and Lubbers Patent neither teach nor suggest monitoring the pH of CSF 48 hours following the initial head trauma, Applicants request withdrawal of the 103 rejection of claims 18 and 28 as they depend either directly or indirectly from claims 10 and 21.

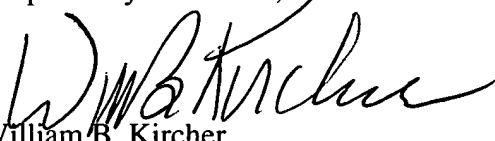
As discussed above, with respect to independent claims 31 and 36, the Kovacs Patent and the Knute Patent neither teach nor suggest a pH sensor within a porous sheath such that CSF flows through the porous sheath and adjacent said sensor. Further, the Bentson Patent and the Lubbers Patent neither teach nor suggest a pH sensor within a porous sheath such that CSF flows through the porous sheath and adjacent said sensor. As stated above, the Bentson Patent teaches an optical fluorescence based sensor for measuring the concentration of a gas in a medium which has improved drift stability and the Lubbers patent teaches a method and an

arrangement for measuring the concentration of gases in a sample including the generation of a monochromatic light beam having predetermined color characteristic.

As the Kovacs Patent, the Knute Patent, the Bentson Patent and the Lubbers Patent neither teach nor suggest a pH sensor within a porous sheath such that CSF flows through the porous sheath and adjacent said sensor, Applicants request withdrawal of the 103 rejection as to claims 35 and 40 which dependent directly or indirectly from independent claims 31 and 36.

Applicants submit that the Application is in condition for allowance and request that a timely notice of allowance be issued in this case. In the Examiner feels that a telephone conference will in any way expedite the advancement of this case, he is asked to call the number listed below at his convenience. The commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment, to Deposit Account No. 19-2112.

Respectfully submitted,

  
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